IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

Ruth Traver,	**Case No. 07-cv-1865-DSD/SRN**
Plaintiff,	
vs.	**ANSWER AND DEFENSES OF DEFENDANT PFIZER INC. TO PLAINTIFF'S COMPLAINT**
Pfizer, Inc.,	**Jury Trial Demanded**
Defendant.	

TO THE HONORABLE JUDGE OF SAID COURT:

NOW COMES Defendant Pfizer Inc. (hereinafter "Pfizer"), incorrectly named as "Pfizer, Inc.", and files this its Original Answer to Plaintiff's Complaint ("Complaint"), and would respectfully show the Court as follows:

I.
PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Plaintiff was prescribed or used Bextra®. Accordingly, this Answer can only be drafted generally. Pfizer may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiff was prescribed and used Bextra®.

II.
ORIGINAL ANSWER

Response to Allegations Regarding Jurisdiction and Venue

1. Pfizer is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning Plaintiff's citizenship and the amount in controversy, and therefore denies them. However, Pfizer admits that Plaintiff claims that the parties are diverse and that the

amount of controversy exceeds $75,000, exclusive of interests and costs. Except as admitted herein, Pfizer denies the allegations contained in Paragraph 1 of Plaintiff's Complaint.

2. Pfizer is without knowledge or information sufficient to form a belief as to the judicial district in which the asserted claims allegedly arose and, therefore, denies that venue is proper in this district pursuant to 28 U.S.C. 1391. Pfizer further denies committing a tort within the State of Minnesota, and denies the remaining allegations contained in Paragraph 2 of the Plaintiff's Complaint.

Response to Allegations Regarding the Parties

3. Pfizer is without knowledge or information sufficient to form a belief as to the truth of to Plaintiff's allegations relating to her state of residence, her medical condition, or her taking of Bextra®. Pfizer denies that Bextra® is defective and denies the remaining allegations contained in Paragraph 3 of Plaintiff's Complaint.

4. Pfizer admits that it is a Delaware corporation with its principal place of business in New York, and that it does business in the State of Minnesota. Further answering, Pfizer admits that, during certain period(s) of time, it marketed and co-promoted Bextra® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. Pfizer denies the remaining allegations contained in Paragraph 4 of Plaintiff's Complaint.

Response to Factual Allegations

5. Pfizer admits that Bextra® (valdecoxib) is a selective Cox-2 inhibitor non-steroidal anti-inflammatory drug (NSAID) which is indicated for relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, and for the treatment of primary dysmenorrhea. Except as admitted herein, Pfizer denies the allegations contained in Paragraph 5 of Plaintiff's Complaint.

6. Pfizer admits that Bextra® is a selective Cox-2 NSAID which is indicated for relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, and for the treatment of primary dysmenorrhea. Pfizer further admits that Bextra® received Food and Drug Administration ("FDA") approval on November 16, 2001.

7. Plaintiff fails to provide the proper context for the allegations contained in Paragraph 7 of Plaintiff's Complaint and, therefore, Pfizer is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 7 of Plaintiff's Complaint. Further answering, Pfizer states that the study analyses speak for themselves and any attempt by Plaintiff to characterize them is denied. Pfizer denies the remaining allegations contained in Paragraph 7 of Plaintiff's Complaint.

8. Plaintiff fails to provide the proper context for the allegations contained in Paragraph 8 of Plaintiff's Complaint regarding "clinical data" and, therefore, Pfizer is without knowledge or information sufficient to form a belief as to the truth of these allegations, and therefore denies them. Pfizer states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Pfizer states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Pfizer denies the remaining allegations contained in Paragraph 8 of Plaintiff's Complaint.

9. Pfizer states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Answering further, Pfizer states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Answering further, Pfizer admits that, during certain periods of time, it marketed and

co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Pfizer denies making any misrepresentations and denies the remaining allegations contained in Paragraph 9 of Plaintiff's Complaint.

10. Plaintiff fails to provide proper context for the allegations contained in Paragraph 10 of Plaintiff's Complaint. Pfizer refers to the information that it provided in a letter to Health Care Professionals on October 15, 2004, which speaks for itself, and any attempt to characterize it is denied. Pfizer denies the remaining allegations contained in Paragraph 10 of Plaintiff's Complaint.

11. Pfizer admits that the sale of Bextra® was voluntarily suspended in the U.S. market as of April 7, 2005, at the request of the FDA. Pfizer denies the remaining allegations contained in Paragraph 11 of Plaintiff's Complaint.

12. Pfizer has insufficient knowledge or information to form a belief as to the truth of Plaintiff's allegations that she took Bextra®, and therefore denies the same. Pfizer admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDAPfizer denies that Bextra® is defective, denies that Bextra® caused Plaintiff injury or damage, and denies the remaining allegations contained in Paragraph 12 of Plaintiff's Complaint.

13. Pfizer denies the allegations contained in Paragraph 13 of Plaintiff's Complaint.

14. Pfizer has insufficient knowledge or information to form a belief as to the truth of Plaintiff's allegations that she took Bextra®, and therefore denies the same. Pfizer states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing

information, which was at all times adequate and comported with applicable standards of care and law. Except as otherwise stated herein, Pfizer denies the allegations contained in Paragraph 14 of Plaintiff's Complaint.

Response to First Cause of Action: Strict Products Liability (Failure to Warn)

15. Pfizer incorporates its responses to each paragraph of Plaintiff's Complaint as if set forth fully herein.

16. Pfizer admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. Pfizer denies the remaining allegations contained in Paragraph 16 of Plaintiff's Complaint.

17. Pfizer states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Pfizer denies the allegations contained in Paragraph 17 of Plaintiff's Complaint.

18. Pfizer states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Pfizer denies the allegations contained in Paragraph 18 of Plaintiff's Complaint.

19. Pfizer states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Pfizer denies that Bextra® is or was defective and denies the remaining allegations contained in Paragraph 19 of Plaintiff's Complaint.

20. Pfizer states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Answering further, Pfizer denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or damages, anddenies the remaining allegations contained in Paragraph 20 of Plaintiff's Complaint, including subparts a, b, and c.

Response to Second Cause of Action: Strict Products Liability (Design Defect)

21. Pfizer incorporates its responses to each paragraph of Plaintiff's Complaint as if set forth fully herein.

22. Pfizer admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. Pfizer denies the remaining allegations contained in Paragraph 22 of Plaintiff's Complaint.

23. Pfizer denies that Bextra® is or was defective and denies the remaining allegations contained in Paragraph 23 of Plaintiff's Complaint.

24. Pfizer denies that Bextra® is or was defective and denies the remaining allegations contained in Paragraph 24 of Plaintiff's Complaint.

25. Pfizer states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Pfizer denies that Bextra® is or was defective and denies the remaining allegations contained in Paragraph 25 of Plaintiff's Complaint.

26. Pfizer states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with

applicable standards of care and law. Pfizer denies that Bextra® is or was defective and denies the remaining allegations contained in Paragraph 26 of Plaintiff's Complaint.

27. Pfizer states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Pfizer denies that Bextra® is or was defective and denies the remaining allegations contained in Paragraph 27 of Plaintiff's Complaint.

28. Pfizer denies that Bextra® is or was defective, denies any wrongdoing, denies that Bextra® caused Plaintff injury or damages, and denies the remaining allegations contained in Paragraph 28 of Plaintiff's Complaint, including subparts a, b, and c.

Response to Third Cause of Action: Negligence

29. Pfizer incorporates its responses to each paragraph of Plaintiff's Complaint as if set forth fully herein.

30. This paragraph contains legal contentions to which no response is required. To the extent that a response is deemed required, Pfizer admits that it has duties as are imposed by law, but denies that it breached any such duties. Pfizer states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Pfizer denies the remaining allegations contained in Paragraph 30 of Plaintiff's Complaint.

31. Pfizer denies the allegations contained in Paragraph 31 of Plaintiff's Complaint.

32. Pfizer states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Pfizer denies the allegations contained in Paragraph 32 of Plaintiff's Complaint.

33. Pfizer states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Pfizer denies the allegations contained in Paragraph 33 of Plaintiff's Complaint.

34. Pfizer denies any wrongful conduct,denies that Bextra® caused Plaintiff any inury or damages, and denies the allegations contained in Paragraph 34 of Plaintiff's Complaint.

Response to Fourth Cause of Action: Breach of Express Warranty

35. Pfizer incorporates its responses to each paragraph of Plaintiff's Complaint as if set forth fully herein.

36. Pfizer states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Pfizer admits that it provided FDA-approved prescribing information about Bextra® and Pfizer denies the remaining allegations contained in Paragraph 36 of Plaintiff's Complaint.

37. Pfizer has insufficient knowledge or information to form a belief as to the truth of Plaintiff's alleged reliance, and therefore denies the same. Pfizer denies the remaining allegations contained in Paragraph 37 of Plaintiff's Complaint.

38. Pfizer states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Pfizer denies the allegations contained in Paragraph 38 of Plaintiff's Complaint.

39. Pfizer denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or damages, and denies the remaining allegations contained in Paragraph 39 of Plaintiff's Complaint.

Response to Fifth Cause of Action: Breach of Implied Warranty

40. Pfizer incorporates its responses to each paragraph of Plaintiff's Complaint as if set forth fully herein.

41. Pfizer admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law, and states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Pfizer admits that it provided FDA-approved prescribing information about Bextra® and denies the remaining allegations contained in Paragraph 41 of Plaintiff's Complaint.

42. Pfizer has insufficient knowledge or information to form a belief as to the truth of Plaintiff's alleged reliance, and therefore denies the same. Pfizer denies the remaining allegations contained in Paragraph 42 of Plaintiff's Complaint.

43. Pfizer states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law, and that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Pfizer denies the allegations contained in Paragraph 43 of Plaintiff's Complaint.

44. Pfizer denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or damages, and denies the remaining allegations contained in Paragraph 44 of Plaintiff's Complaint.

Response to Sixth Cause of Action: Fraudulent Concealment

45. Pfizer incorporates its responses to each paragraph of Plaintiff's Complaint as if set forth fully herein.

46. This paragraph contains legal contentions to which no response is required. To the extent that a response is deemed required, Pfizer admits that it has duties as are imposed by law, but denies that it breached any such duties. Pfizer denies that Bextra® is defective, denies concealing information, and denies the remaining allegations contained in Paragraph 46 of Plaintiff's Complaint.

47. This paragraph contains legal contentions to which no response is required. To the extent that a response is deemed required, Pfizer admits that it has duties as are imposed by law, but denies that it breached any such duties. Pfizer denies the remaining allegations contained in Paragraph 47 of Plaintiff's Complaint.

48. Pfizer denies any wrongful conduct and denies the remaining allegations contained in Paragraph 48 of Plaintiff's Complaint.

49. Pfizer states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Pfizer denies the remaining allegations contained in Paragraph 49 of Plaintiff's Complaint.

50. Pfizer denies any concealment or suppression of facts, denies that Bextra® caused Plaintiff any injury or damages, and denies the remaining allegations contained in Paragraph 50 of Plaintiff's Complaint.

Response to Seventh Cause of Action:
Violation of the Uniform Deceptive Trade Practices Act

51. Pfizer incorporates its responses to each paragraph of Plaintiff's Complaint as if set forth fully herein.

52. Paragraph 52 of Plaintiff's Complaint states legal conclusions to which no response is required.

53. Pfizer denies any wrongful conduct and denies the allegations contained in Paragraph 53 of Plaintiff's Complaint.

54. Pfizer denies any wrongful conduct and denies the allegations contained in Paragraph 54 of Plaintiff's Complaint.

55. Pfizer states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Pfizer states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Pfizer denies making false representations or concealing information, and denies the remaning allegations contained in Paragraph 55 of Plaintiff's Complaint.

56. This paragraph contains legal contentions to which no response is required. To the extent that a response is deemed required, Pfizer denies any wrongful conduct and denies the allegations contained in Paragraph 56 of Plaintiff's Complaint.

57. Pfizer denies any wrongful conduct and denies the allegations contained in Paragraph 57 of Plaintiff's Complaint.

58. This paragraph contains legal contentions to which no response is required. To the extent that a response is deemed required, Pfizer denies making any misrepresentations or concealing information, and denies the remaining allegations contained in Paragraph 58 of Plaintiff's Complaint.

59. Pfizer denies any wrongful conduct, denies that Bextra® cause Plaintiff any injury or damages, and denies the allegations contained in Paragraph 59 of Plaintiff's Complaint.

Response to Eighth Cause of Action: Unjust Enrichment

60. Pfizer incorporates its responses to each paragraph of Plaintiff's Complaint as if set forth fully herein.

61. Pfizer is without knowledge or information to form a belief as to the truth of the allegations of Paragraph 61, and therefore denies the same.

62. Pfizer states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Pfizer denies the allegations contained in Paragraph 62 of Plaintiff's Complaint.

63. Pfizer states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Pfizer denies the allegations contained in Paragraph 63 of Plaintiff's Complaint.

Response to Prayer for Relief

Pfizer specifically denies that its is liable to Plaintiff for any type of damages, in any amount, and further denies the remaining allegations in the Prayer for Relief, including subparts 1 thorough 7.

III.
GENERAL DENIAL

Pfizer denies all allegations and/or legal conclusions set forth in Plaintiff's Complaint that have not been previously admitted, denied, or explained.

IV.
AFFIRMATIVE DEFENSES

Pfizer reserves the right to rely upon any of the following or additional defenses to claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Pfizer affirmatively shows that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendant's labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiff's causes of action against Defendant, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendant provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendant's warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiff's claims are barred and/or limited by the provisions of the Minnesota Statutes.

Sixth Defense

6. Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is plead in full bar of any liability as to Defendant.

Seventh Defense

7. Plaintiff's action is barred by the statute of response.

Eighth Defense

8. Plaintiff's claims against Defendant are barred to the extent Plaintiff was contributorily negligent, actively negligent or otherwise failed to mitigate her damages, and any recovery by Plaintiff should be diminished accordingly.

Ninth Defense

9. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendant. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendant and for whose acts or omissions Defendant is not liable in any way.

Tenth Defense

10. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendant cannot be liable.

Eleventh Defense

11. Any injuries or expenses incurred by Plaintiff were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Twelfth Defense

12. Defendant affirmatively denies that they violated any duty owed to the Plaintiff.

Thirteenth Defense

13. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product.

Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiff's treating and prescribing physicians.

Fourteenth Defense

14. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fifteenth Defense

15. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

Sixteenth Defense

16. Plaintiff's causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Seventeenth Defense

17. Plaintiff's alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Bextra® after the product left the control of Defendant and any liability of Defendant is therefore barred.

Eighteenth Defense

18. Plaintiff's alleged damages were not caused by any failure to warn on the part of Defendant.

Nineteenth Defense

19. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Bextra®.

Twentieth Defense

20. Plaintiff knew or should have known of any risk associated with Bextra®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twenty-first Defense

21. Plaintiff is barred from recovering against Defendant because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-second Defense

22. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-third Defense

23. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-sixth Defense

26. Plaintiff's claims are barred in whole or in part because Defendant provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-seventh Defense

27. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-eighth Defense

28. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Thirtieth Defense

30. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirty-first Defense

31. The imposition of punitive damages in this case would violate Defendant's rights to procedural due process under both the Fourteenth Amendment of the United States Constitution and Article I, § 17 of the Constitution of the State of Minnesota, and would additionally violate Defendant's right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-second Defense

32. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution and are subject to all provisions of Minnesota law, including but not limited to Minnesota Statute 549.191.

Thirty-third Defense

33. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-fourth Defense

34. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fifth Defense

35. In the event that reliance was placed upon Defendant's nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendant.

Thirty-sixth Defense

36. Plaintiff failed to provide Defendant with timely notice of any alleged nonconformance to any express representation.

Thirty-seventh Defense

37. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendant's rights under the United States Constitution.

Thirty-eighth Defense

38. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-ninth Defense

39. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitution of the State of Minnesota. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive-damages based on out-of state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits

recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendant; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, Pacific Mutual Life Ins. Co. v. Haslip, 499 U.S. 1, 111 (1991), TXO Production Corp. v. Alliance Resources, Inc., 509 U.S. 443 (1993); BMW of North America, Inc. v. Gore, 519 U.S. 559 (1996); and State Farm Mut. Auto Ins. Co. v. Campbell, 538 U.S. 408 (2003).

Fortieth Defense

40. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Forty-first Defense

41. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured and labeled in accordance with the state-of-the art industry standards existing at the time of the sale.

Forty-second Defense

42. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or

apparent authority to take said actions on behalf of Defendant and over whom Defendant had no control and for whom Defendant may not be held accountable.

Forty-third Defense

43. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-fourth Defense

44. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fifth Defense

45. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendant's conduct.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiff.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendant's conduct.

Forty-eighth Defense

48. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the

applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-ninth Defense

49. The claims must be dismissed because Plaintiff would have taken Bextra® even if the product labeling contained the information that Plaintiff contend should have been provided.

Fiftieth Defense

50. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

Fifty-first Defense

51. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-second Defense

52. Defendant's liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendant seeks an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

Fifty-third Defense

53. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-forth Defense

54. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fifth Defense

55. Defendant reserves the right to supplement its assertion of defenses as it continues with its factual investigation of Plaintiff's claims.

V.
JURY DEMAND

Defendant hereby demands a trial by jury.

VI.
PRAYER

WHEREFORE, Pfizer prays that Plaintiff take nothing by her suit, that Pfizer be discharged with its costs expended in this matter, and for such other and further relief to which Pfizer may justly be entitled.

Dated: May 2, 2007

Respectfully submitted,

FAEGRE & BENSON LLP

/s/ Joseph M. Price

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